

IMMUNOASSAY SPECIALITY I - LEVEL 2 (IA SPECIALITY I LEV 2)

CAT. NO. IAS3114

LOT NO. 1796EC

SIZE: 5 x 2 ml

EXPIRY: 2020-04-28

GTIN: 05055273207309

INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of the accuracy of Immunoassays on clinical chemistry systems. This material can be used to monitor the control of accuracy or the control of reproducibility of immunoassays.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 5 days at +2°C to +8°C if kept capped in original container and free from contamination, or 4 weeks frozen once at -20°C. Anti-TG is stable for 3 days at +2°C to +8°C. C-Peptide, IGF-I and Procalcitonin are stable for 1 day at +2°C to +8°C. Osteocalcin is stable for 4 hours at +2°C to +8°C. Parathyroid Hormone (PTH) should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored below -20°C.

Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. If bacterial contamination is suspected, the vial should be discarded and a fresh vial reconstituted.

PREPARATION

The Immunoassay Speciality I Control is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 2 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Immunoassay Speciality I - Level 2 5 x 2 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Immunoassay Speciality I Control is submitted to a number of reference laboratories and values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean ± 2 S.D. This results in extremely accurate values, which may be confidently used by laboratories to ensure the accuracy of their methods.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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Analyte	unit	Target	Range		methods
			low	high	
1-25 (OH) ₂ Vitamin D	pmol/l	156	109	203	IDS iSYS
25-OH Vitamin D	nmol/l	114	85.5	143	Roche Vitamin D Total
	nmol/l	123	92.3	154	Diasorin Liaison
	nmol/l	117	87.8	146	Abbott Architect
	nmol/l	149	112	186	Siemens Centaur XP/XPT/Classic
	nmol/l	112	84.0	140	BioMerieux Vidas
	nmol/l	123	92.3	154	Roche Vitamin D Total II
Anti-TG	kU/l	296	222	370	Siemens Immulite 2000/2500
	kU/l	865	649	1081	Roche Modular E170
	kU/l	153	115	191	Abbott Architect
	kU/l	971	728	1214	Roche Cobas E411
	kU/l	882	662	1103	Roche Cobas 6000/8000
	kU/l	548	411	685	Beckman Dxl 600/800
	kU/l	1298	974	1623	Siemens Centaur XP/XPT/Classic
Anti-TPO	kU/l	64.9	48.7	81.1	Roche Modular E170
	kU/l	90.5	67.9	113	Abbott Architect
	kU/l	101	75.8	126	Siemens Immulite 2000/2500
	kU/l	74.0	55.5	92.5	Roche Cobas E411
	kU/l	72.0	54.0	90.0	Roche Cobas 6000/8000
	kU/l	75.8	56.9	94.8	Beckman Dxl 600/800
	kU/l	309	232	386	Siemens Centaur XP/XPT/Classic
C-Peptide	nmol/l	1.130	0.848	1.410	Siemens Centaur XP/XPT/Classic
	ng/ml	3.41	2.56	4.26	
	nmol/l	1.560	1.170	1.950	Roche Cobas 6000/8000
	ng/ml	4.71	3.53	5.89	
	nmol/l	1.350	1.010	1.690	Abbott Architect
	ng/ml	4.08	3.05	5.11	
	nmol/l	1.430	1.070	1.790	Siemens Immulite 2000/2500
	ng/ml	4.32	3.23	5.41	
IGF-1	nmol/l	1.490	1.120	1.860	Roche Cobas E411
	ng/ml	4.50	3.38	5.62	
	ng/ml	4.50	3.38	5.62	
IGF-1	µg/l	237	178	296	Siemens Immulite 2000/2500
	µg/l	206	155	258	Diasorin Liaison
	µg/l	291	218	364	Siemens Immulite 1000
Insulin	mU/l	14.9	11.2	18.6	Abbott Architect
	µU/ml	14.9	11.2	18.6	
	mU/l	18.9	14.2	23.6	Roche Cobas 6000/8000
	µU/ml	18.9	14.2	23.6	
	mU/l	16.1	12.1	20.1	Siemens Centaur XP/XPT/Classic
	µU/ml	16.1	12.1	20.1	
	mU/l	13.9	10.4	17.4	Beckman Dxl 600/800
µU/ml	13.9	10.4	17.4		

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			low	high	
Insulin	mU/l	18.3	13.7	22.9	Roche Cobas E411
	µU/ml	18.3	13.7	22.9	
Osteocalcin	µg/l	49.3	37.0	61.6	Siemens Immulite 2000/2500
	µg/l	86.4	64.8	108	Roche Cobas 6000/8000
	µg/l	89.4	67.1	112	Roche Cobas E411
	µg/l	103	77.3	129	Diasorin Liaison
Parathyroid Hormone (PTH)	pmol/l	27.4	20.6	34.3	Roche Modular E170 PTH/PTH STAT
	pg/ml	260	196	324	
	pmol/l	40.6	30.5	50.8	Abbott Architect
	pg/ml	386	290	482	
	pmol/l	30.7	23.0	38.4	Beckman Dxl 600/800
	pg/ml	292	218	366	
	pmol/l	46.5	34.9	58.1	Siemens Immulite 2000/2500
	pg/ml	442	331	553	
	pmol/l	27.1	20.3	33.9	Roche Cobas 6000/8000
	pg/ml	257	193	321	
pmol/l	28.9	21.7	36.1	Roche Cobas 4000/e411 PTH/PTH STAT	
pg/ml	274	206	342		
Procalcitonin	pmol/l	39.9	29.9	49.9	Siemens Centaur XP/XPT/Classic
	pg/ml	379	284	474	
	µg/l	1.98	1.49	2.48	Brahms Kryptor
	µg/l	4.42	3.32	5.53	BioMerieux Vidas
	µg/l	2.86	2.15	3.58	Roche Elecsys/Cobas/Modular
	µg/l	4.31	3.23	5.39	Siemens Centaur XP/XPT/Classic
µg/l	4.64	3.48	5.80	Siemens Centaur CP	
µg/l	4.17	3.13	5.21	Diazyme PCT	